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Office of Legislative Counsel

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21 APR 1978

Mr. James M. Frey
Assistant Director for
Legislative Reference
Office of Management and Budget
Washington, D.C. 20503


Dear Mr. Frey:

Enclosed is a proposed report to Chairman Williams, Senate Committee on Human Resources, in response to a request for our recommendations on S. 2579, a bill "To amend the Public Health Service Act to establish the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and for other purposes."

Advice is requested as to whether there is any objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

SIGNED


Acting Legislative Counsel

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Enclosure

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Washington, D.C. 20505

Honorable Harrison A. Williams, Chairman
Committee on Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

I am writing in response to your request for the views of this Agency on S. 2579, a bill "To Amend the Public Health Service Act to establish a President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and for other purposes."

The proposed bill would establish a Presidential Commission to guarantee that the rights of human subjects of biomedical and behavioral research are protected. Current CIA guidelines require that human subject research be conducted in strict accordance with Department of Health, Education and Welfare regulations and applicable statutes and that each entity conducting research hold an approved assurance from HEW. Thus, existing Agency policy is in accord with the aims of this legislation; and, in general, I have no objections to the framework the bill would establish. There are, however, several issues, including some relating to the handling of sensitive information, which I must raise with your Committee.

Proposed subsection 1801(e) states that each prospective member of the Commission "shall receive all department and agency security clearances" necessary to assure access to information. This reads as if receipt of the clearances is a matter of right. This certainly is not the case, nor do I believe it is the intent of the bill. Substituting instead the phrase "must have qualified for all appropriate department and agency security clearances," would place this provision in the appropriate context.

The provisions of proposed subsection 1801(e) recognize the need for protecting national security information from unauthorized disclosure. Such information may fall into two categories: that which is classified pursuant to criteria established by Executive Order, and that which is designated pursuant to the statutory responsibility of the Director of Central Intelligence (50 U.S.C. section 403(d)(3)) as information involving intelligence sources and methods. Proposed subsection 1801(f) provides that the current National Commission will remain in existence until the

new Presidential Commission is established and that members of the current National Commission shall not have access to classified information until they have obtained appropriate security clearances. This prohibition covers only one category of national security information, and its protection should be expanded by amending line 7 of the subsection to read as follows:

"no classified information or information protected from unauthorized disclosure by statute shall be made available to such. . ."

Several of the provisions of the bill, such as proposed sections 1802, 1803, 1804 and 1805, require that the Commission issue reports. In addition, proposed subsection 1806(d) provides the Commission with broad authority to make information public, and proposed subsection 1806(e) calls for publication of certain information in the Federal Register. Proposed section 1807 limits these provisions by restraining the Commission from disclosing trade secrets and commercial or financial information and individually identifiable personal data. There is, however, no prohibition on disclosure of national security information to which the Commission may have access. S. 1893, this bill's predecessor, included language prohibiting the Commission from disclosing classified information, and failure to include such a prohibition in this bill could be argued to be tacit consent to disclosure. Further, as outlined above, even a restriction on disclosure of classified information would not protect all national security information. In order to make the extent of the Commission's authority perfectly clear, I suggest that the following new subsection be added to proposed section 1807:

"(c) The Commission shall not disclose any information collected or maintained by it pursuant to this title which is properly classified or is protected from unauthorized disclosure by statute."

A further problem arises from the grant of authority to the Commission to hire various categories of personnel contained in proposed paragraphs 1806(b)(1), (2) and (3). Once hired, such persons undoubtedly will have access to information in the possession of the Commission. There is no requirement, however, that these persons be required to obtain security clearances; nor are there any prohibitions on their releasing information. A provision stating that such persons are subject to the same security requirements and restrictions as the members of the Commission should be added to the bill.

The bill would also require the Commission to make recommendations to each agency or department engaged in biomedical or behavioral research. I support this approach because the Commission could be expected to take

a broad view of Government research in making its recommendations. In this manner, the unique requirements and interests of each entity conducting research could more effectively be taken into account in determining guidelines for the manner in which it conducts its research. Those agencies and departments heavily involved in the types of research covered by the bill could certainly give advice and counsel to the Commission.

Further, I believe that all agencies and departments engaged in biomedical and behavioral research should be allowed to designate an ex officio advisor to the Commission. This would insure that each has a representative sensitive to its needs who can plead its case before the Commission.

The Office of Management and Budget has advised there is no objection to the submission of this report from the standpoint of the Administration's program.

Thank you for the opportunity to comment on this legislation.

Sincerely,

Frank C. Carlucci